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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,289	01/24/2006	Shizuka Uehara	P27716	4829
7055 7590 04/23/2009 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191				
EXAMINER HOFFMAN, SUSAN COE				
ART UNIT 1655		PAPER NUMBER		
NOTIFICATION DATE 04/23/2009		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/531,289

Applicant(s)

UEHARA ET AL.

Examiner

Susan Coe Hoffman

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 19, 20 and 25-35 is/are pending in the application.
- 4a) Of the above claim(s) 27-29, 31 and 33-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 19, 20, 25, 26, 30 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 9, 2009 has been entered.
2. Claims 27-35 have been added in this amendment.
3. Claims 16, 19, 20, and 25-35 are currently pending.
4. The declarations of Taku Hoshino and Chiharu Koide, both filed March 9, 2009, have been considered.
5. In the reply filed June 30, 2008, applicant elected *Glycyrrhiza glabra* extract for the species with traverse.
6. Claims 27-29, 31 and 33-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.
7. Claims 16, 19, 20, 25, 26, 30 and 32 are examined on the merits solely in regards to the elected species.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 16, 19, 20, 25, 26, 30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamai (US 6,313,214) and Hadas (US 5,609,875).

Tamai teaches the compounds claimed as ingredient (A), formula 1. The reference teaches that these compounds can be extracted from the plants claimed in claims 19 and 20. The reference teaches that these compounds are used to treat skin aging by lightening the skin (see claims, column 1, lines 21-28, and column 2, line 57-end). The reference teaches using the compounds in various amounts ranging from 0.01 to 10% (see column 5, lines 6-17). The reference does not teach using *Glycyrrhiza glabra* extract in the composition.

Hadas teaches using *Glycyrrhiza glabra* extract for lightening the skin. The extract is used in various amounts ranging from 0.005 to 5% (see column 1, last paragraph and claims).

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions that lighten the skin. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In *re* Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In *re* Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In *re* Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in compositions to lighten the skin, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to lighten the skin. Therefore, the artisan would have been motivated to combine the claimed ingredients into

a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186. Since Tamai teaches that skin lightening preparations are useful in treating skin aging, an artisan of ordinary skill would reasonably expect that using the skin lightening preparation taught by Tamai and Hadas to treat skin aging would be successful. This reasonable expectation of success would motivate the artisan to treat skin aging using the combination of ingredient (A) and *G. glabra*.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The references teach that each of the claimed ingredients is a cosmetically active ingredient useful for skin lightening. An artisan of ordinary skill would routinely modify the amount of cosmetically active ingredients based on the patient's skin condition, skin sensitivity and degree of lightening needed. In addition, as discussed above, each reference also teaches using the ingredients in a variety of ranges. This shows that the references acknowledge that the ingredient amount can be varied. Therefore, an artisan would have been motivated to modify the amount of each ingredient in the combination in order to formulate a product that best achieves the desired results set forth in the references. Thus, absent some

demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Response to Arguments

All of applicant's arguments filed March 9, 2009 have been fully considered but they are not persuasive. Applicant argues that the data presented in the declaration of Chiharu Koide show that the claimed composition produces unexpected results. However, these results are not considered to support a claim for unexpected results because the results shown are not commensurate in scope with the claimed invention. As discussed in MPEP section 716.02(d):

Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. In re Clemens, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980).

Applicant's claims 16, 19, 20, 25, 26 and 30 are not limited to any particular range. Thus, the claims are of broad scope and encompass a very broad range. The results shown in the declaration are not commensurate in scope with the claimed invention because they only show unexpected results for one data point per combination. The results only show one data point for the combination of *G. glabra* with *Cistus ladaniferus* extract, the acid mixture, the methyl ester mixture, the ethyl ester mixture, Compound 1, Compound 4 and Compound 7. The showing of one data point for these combinations is not considered to support unexpected results over the entire breadth of claims 16, 19, 20, 25, 26 and 30. In addition, the results do not show the combination of *G. glabra* with *C. creticus*, *C. monspeliensis* and *C. salvifolius*. Furthermore, while claim 32 is limited to a specific range for each ingredient, the showing of one data point is

not considered to support a claim for unexpected results over this entire range. In addition, applicant's data does not appear to correspond to the mass percentages claimed in claim 32. Thus, the data does not appear to directly correlate with the ranges claimed in claim 32. Therefore, because applicant's data has not shown unexpected results commensurate in scope with the broadly claimed invention, the claims are still considered to be properly rendered obvious by the combination of the references.

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Coe Hoffman/
Primary Examiner, Art Unit 1655